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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/160,076      | 09/24/1998  | DAVID W. SCOTT       | 308072000110        | 5918             |

25226 7590 12/17/2003

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| EXAMINER |
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WILSON, MICHAEL C

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| ART UNIT | PAPER NUMBER |
|----------|--------------|

1632

45

DATE MAILED: 12/17/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/160,076

Applicant(s)

SCOTT ET AL.

Examiner

Michael C. Wilson

Art Unit

1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 69-81 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 69-81 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

The rejection sent 8-28-03 has been vacated in favor of the instant office action. This is in response to a phone call to Practice Specialist George Elliott by Applicants' representative. The rejections under 102 have been clarified in this office action. Rejections withdrawn in the office action of 8-28-03 have been omitted in this office action for clarity. This office action is non-final. The referenced cited in the office action of 8-28-03 will not be resent with this office action. Claims 69-81 remain pending and under consideration in the instant application. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action. Applicant's arguments filed 5-30-03, paper number 42, are discussed herein.

#### ***Specification***

The first line of the specification needs updated to reflect that parent application 08/195874 is now US Patent 5,817,308.

The blanks on pg 16 must be filled in.

The title should be changed to reflect the claims are directed toward cells expressing fusion proteins of immunoglobulins.

#### ***Priority***

The claim for domestic priority to 08/195874, now US Patent 5,817,308, is acknowledged.

***Claim Rejections - 35 USC § 112***

1. Claim 70, 72 and 74 remain rejected and claims 80 and 81 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 70 is indefinite as newly amended because it is not clear that the nucleic acid sequence in claim 69 was introduced into the cell. The phrase “wherein said nucleic acid sequence is a viral vector” would overcome this rejection.

Claim 72 is indefinite as newly amended because claim 69 is not directed toward a fusion protein and because the claim is dependent on two claims for two different things. Overall, the structure of the limitation is unclear. The phrase “wherein there are two or more copies of said nucleic acid sequence” would overcome this rejection.

The phrase “the first framework region of said N-terminal variable region” (claim 74) lacks antecedent basis in parent claims 69 or 70. It is not clear “the first framework region” must occur in the “N-terminal variable region” in parent claims 70 or 69. What is a “framework region”?

The term “autoimmune antigen” (claim 80) is indefinite for reasons of record regarding autoantigen.

Claim 81 is indefinite. The term “allergan” cannot be found in the art. The term is not defined in the dictionary or in the specification.

***Claim Rejections - 35 USC § 102***

2. Claims 69 and 79-81 are rejected under 35 U.S.C. 102(b) as being anticipated by McDonnell et al. (Cell, 1989, Vol. 57, pg 79-88).

McDonnell taught a transgenic mouse whose genome comprised a transgene comprising bcl-2-Ig fusion protein. Splenocytes and thymocytes were isolated from the mice in saline and media. The splenocytes and thymocytes are non-tumor lymphoid cells and are equivalent to the composition claimed because they have the structure claimed. The bcl-2-Ig fusion protein is equivalent to the fusion protein required in the claim because it has a heavy chain immunoglobulin and bcl-2. The bcl-2 protein inherently has at least one epitope as claimed. The cells of McDonnell inherently "induces tolerance to an antigen" because it has the same structure as the cell claimed. The phrase "for introduction into an individual" does not bear patentable weight because they are intended uses and may not occur. These intended uses do not bear patentable weight because they do not alter the structure of the composition. The composition of McDonnell inherently meets the functional limitation of "wherein upon introduction to the individual said composition induces tolerance to the antigen in the individual" because it has the structure claimed. The splenocytes and thymocytes inherently comprise "hematopoietic cells" (claim 79) because they comprise pluripotent cells capable of differentiation. Claims 80 and 81 are included because the metes and bounds of the limitations cannot be determined (see 112/2nd); therefore, bcl-2 is an autoimmunogen and an allergan.

Art Unit: 1632

***Double Patenting***

3. Claim 75 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 70. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). Both claims require the nucleic acid is introduced into the cell via a viral vector.

***Conclusion***

No claim is allowed.

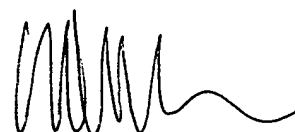
Inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Wilson who can normally be reached on Monday through Friday from 9:00 am to 5:30 pm at (703) 305-0120. The Examiner's number will be changed on January 12<sup>th</sup>, 2004 to 571-272-0738.

Questions of a general nature relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-1235.

If attempts to reach the examiner, patent analyst or Group receptionist are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached on (703) 305-4051.

The official fax number for this Group is (703) 872-9306.

Michael C. Wilson



MICHAEL WILSON  
PRIMARY EXAMINER